Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Paul E. Plunkett	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	98 C 4293	DATE	9/13/2001
CASE TITLE	WARNER-LAMBERT COMPANY vs. APOTEX CORP.,et al		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] ENTER MEMORANDUM OPINION AND ORDER: there is no genuine issue of material fact on plaintiff's claim that defendant's proposed gabapentin product will infringe the '479 patent. Accordingly, defendants are entitled to judgment as a matter of law on the second patent infringement claim plaintiff asserts against them. Defendant's motion for summary judgment on that claim is, therefore, granted. This is a final and appealable order. The pending motion to reconsider denial of motion to transfer is denied as moot. Briefing schedule and ruling date of 10/2/01 on moton to reconsider are stricken.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.			
	Notices mailed by judge's staff.		SEP 14 2001 date docketed	
	Notified counsel by telephone.			
✓	Docketing to mail notices.		docketing deputy initials	
✓	Mail AO 450 form.	ED: 7 FILED FOR DOCKETING 01 SEP 13 PM 2:54		
	Copy to judge/magistrate judge.		date mailed notice	
TBK	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WARNER-LAMBERT COMPANY,	)	
	)	
Plaintiff,	)	
v.	)	**No. 98 C 4293**
	)	**Paul E. Plunkett, Senior Judge**
APOTEX CORP., APOTEX, INC., and TORPHARM, INC.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff sued defendants for their alleged infringement of two patents. On March 2, 2001, the Court granted summary judgment to defendants on the infringement claim concerning U.S. Patent No. 4,894,476. Defendants have now filed a motion for summary judgment on plaintiff's claim for infringement of U.S. Patent No. 5,084,479. For the reasons set forth below, the motion is granted.

Facts

Plaintiff is the assignee of two expired patents: (1) U.S. Patent No. 4,024,175, which discloses and claims the compound gabapentin; and (2) U.S. Patent No. 4,087,544, which discloses and claims a method of treating certain forms of epilepsy using gabapentin. (Pl.'s LR 56.1(b)(3)(A) Stmt.¶¶ 15-19.) Because both patents have now expired, gabapentin and its use in the treatment of epilepsy are now in the public domain. (Id. ¶ 20.)

Plaintiff is also the holder of a New Drug Application ("NDA") for gabapentin, which it sells under the trade name Neurontin. (Id. ¶¶ 9-10.) The FDA has approved gabapentin only for use "as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." (Id. ¶ 11.)

Plaintiff is also the assignee of U.S. Patent No. 5,084,479 ("the '479 patent"), which discloses and claims the use of gabapentin for treating neurodegenerative diseases including stroke, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis and Parkinson's disease. (Id. ¶¶ 21-24.) The FDA has not approved gabapentin for any of the uses claimed in the '479 patent. (Id. ¶ 25.)

In April 1998, defendant TorPharm, Inc.,[1] a Canadian corporation that manufactures generic drugs for sale in the United States, sought the FDA's approval to market generic gabapentin capsules solely for use in the treatment of epilepsy. (Id. ¶¶ 4, 28-29, 31.) The Abbreviated New Drug Application ("ANDA") TorPharm submitted to the FDA included a certification that TorPharm's generic gabapentin product would not infringe the '479 patent because it is not labeled for use in the treatment of neurodegenerative diseases. (Id. ¶¶ 33, 34.)

A month later, TorPharm notified plaintiff that it had filed an ANDA for its gabapentin. The notice said:

> The following is TorPharm's factual and legal basis for the statement that the ['479] patent will not be infringed. The manufacture, use or sale of TorPharm's Gabapentin does not fall within the scope of any of the claims of [the '479 patent] .... All of the claims of the '479 patent are directed to a method of using gabapentin and its derivatives in the treatment of neurodegenerative diseases such as stroke, Alzhei-

[1]Defendant Apotex Corp. is the United States marketing and sales affiliate for TorPharm, Inc. (Pl.'s LR 56.1(b)(3)(A) Stmt. ¶ 47.) The record does not disclose what relationship, if any, defendant Apotex, Inc. currently has to Apotex Corp. and TorPharm, Inc.

mer's disease, Huntington's disease, amyotrophic lateral sclerosis, and Parkinson's disease. TorPharm's indicated use for its pharmaceutical product is partial seizure. The '479 patent does not claim a method of using gabapentin and its derivatives for partial seizure. Moreover, partial seizure is not a neurodegenerative disease.

(Id. ¶¶ 35-36; Defs.' LR 56.1(a)(3) Stmt., Ex. 11, 5/19/98 Cert. Noninfringement.)[2]

Though gabapentin has been approved by the FDA solely for use in treating epilepsy, doctors are not required to prescribe the medication only for that purpose. (Smith Decl., Ex. 5, Sutula Report at 8-9.) Rather, doctors can prescribe approved drugs for indications other than those listed on the label. (Id.) Such "off-label" use is supported by both the FDA and the American Medical Association. (Id. at 9.)

By October 1998, plaintiff had sold more than $890 million of Neurontin. (Defs.' Resp. Pl.'s LR 56.1 (b)(3)(B) Stmt. ¶¶ 11-12.) Only about 22% of those sales were for the treatment of epilepsy. (Id. ¶ 12.) The remaining 78% were for off-label use, including the treatment of neurodegenerative diseases. (Id.)

Pharmacists and other drug-dispensing organizations commonly substitute generic drugs for name brand drugs unless they are instructed by a physician not to do so. (Id. ¶ 18.) As a result, plaintiff contends, TorPharm's proposed gabapentin product will be substituted by pharmacists for Neurontin for patients being treated for neurodegenerative diseases, thereby infringing the '479 patent.

---

[2]Plaintiff filed this action within forty-five days of receiving this notice, which suspended FDA approval of TorPharm's ANDA for its generic gabapentin product until the earliest of the following: (1) the date the Court decides the patent is invalid or not infringed; (2) the date the patent expires, if the Court decides it is valid and infringed; or (3) thirty months from the patent owner's receipt of the notice of noninfringement. 21 U.S.C. § 355(j)(5)(B)(iii).

The Legal Standard

To prevail on a summary judgment motion, "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, [must] show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). At this stage, we do not weigh evidence or determine the truth of the matters asserted. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). We view all evidence and draw all inferences in favor of the non-moving party. Michas v. Health Cost Controls of Illinois, Inc., 209 F.3d 687, 692 (7th Cir. 2000). Summary judgment is appropriate only when the record as a whole establishes that no reasonable jury could find for the non-moving party. Id.

Discussion

Plaintiff contends that defendants' manufacture and sale of their generic gabapentin product will induce infringement of the '479 patent.[3] To succeed on this claim, plaintiff must prove that defendants' "actions induced infringing acts *and* that [they] knew or should have known [their] actions would induce actual infringements." Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990) (emphasis in original).[4] It is not enough that defendants have "knowledge of the acts alleged to constitute inducement." Id. Rather, plaintiff must show that defendants had

[3]Plaintiff does not contend that defendants have violated 35 U.S.C. § 271(e)(2)(A), which prohibits the submission of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." Such a claim would, in any event, be foreclosed by TorPharm's ANDA, which seeks FDA approval for a gabapentin product to be used solely for epilepsy. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1248-49 (Fed. Cir. 2000) (holding that defendant's ANDA, which specified a drug with characteristics not claimed by plaintiff's patent, "mandate[d] a finding of no literal infringement" under 35 U.S.C. § 271(e)(2)(A)).

[4]Both parties assume the existence of direct infringement.

the "specific intent to encourage another's infringement." Id.; see 35 U.S.C. § 271(b) ("Whoever actively induces infringement of a patent shall be liable as an infringer.").

There is no evidence that defendants actively encouraged doctors to prescribe their product for neurodegenerative diseases. TorPharm does not market or distribute any of its products in the United States. (Pl.'s LR 56.1(b)(3)(A) Stmt. ¶ 41.)[5] It does not employ a sales force, it does not publish advertisements in medical journals, it does not fund research on gabapentin and it does not fund professional meetings where doctors might discuss gabapentin and its uses. (Id. ¶¶ 41, 45-46.)[6] All of the marketing and distribution of TorPharm's products in the United States is done by Apotex Corp. (Id. ¶ 41.) Apotex Corp. markets TorPharm's products to wholesalers, warehousing chains, mail order organizations and group purchasing organizations. (Id. ¶ 48.) It does not market any of TorPharm's products directly to doctors. (Id. ¶ 49.)[7] Apotex Corp.'s advertisements, which are placed in sales and marketing pharmaceutical journals, do not encourage any specific use for TorPharm's drugs. (Id. ¶¶ 50-52.)[8] Apotex Corp. has not researched off-label uses of gabapentin and has not funded any research on gabapentin or any professional meetings where doctors might discuss gabapentin and its uses. (Id. ¶¶ 55-56.)[9] Moreover, plaintiff's own expert opined that doctors learn about off-label uses from professional meetings and conferences, formal studies,

---

[5]Because plaintiff denied this fact without any citation to the record, it is deemed to have admitted it. See LR 56.1(b)(3)(A), (B).

[6]See n.5.

[7]See n.5.

[8]See n.5.

[9]See n.5.

medical literature, case reports and discussions with colleagues, not from drug companies. (Id. ¶¶ 57-62.) In short, there are no facts to suggest that defendants took any steps to encourage doctors to write gabapentin prescriptions for neurodegenerative diseases.

Plaintiff argues, however, that defendants knew or should have known that their proposed gabapentin product would induce doctors to infringe the '479 patent because: (1) doctors prescribe gabapentin for off-label use, including for the treatment of neurodegenerative diseases; and (2) pharmacists routinely substitute generic drugs for brand name drugs.[10] The Court disagrees. These facts, though necessary to support the inference that defendants knew their product would induce infringement, are not sufficient to do so. To defeat this motion, plaintiff must also have facts to suggest that defendants *knew* doctors were prescribing gabapentin for the neurodegenerative diseases covered by the '479 patent.

Plaintiff has no such evidence. Dr. Sherman, who made the decision to develop TorPharm's gabapentin product, testified that he was not aware of any off-label uses of gabapentin when he made that decision. (Defs.' LR 56.1(a) Stmt. ¶¶ 38-40; Pl.'s LR 56.1(b)(3)(B) ¶ 33.) That testimony is suspect, plaintiff says, because "data showing the breakdown of [Neurontin] sales by uses was readily available to [defendants] from publications and commercial data bases subscribed to by most pharmaceutical companies." (Pl.'s LR 56.1(b)(3)(B) Stmt. ¶ 38.) But the fact that defendants could have obtained such information does not mean that they did. According to the record, the only information Dr. Sherman gleaned from trade literature was the amount of Neurontin plaintiff sold

[10]Though defendants have not admitted knowledge of this undisputed practice, it is reasonable to infer that they, as manufacturers and distributors of generic drugs sold in the United States, would be aware of it.

annually. (Smith Decl., Ex. 13, Sherman Dep. at 4-5.)[11] He did not say, and the record does not otherwise suggest, that the literature he reviewed described the specific conditions for which Neurontin was prescribed. Moreover, though it might be reasonable to infer that Dr. Sherman, as CEO of a pharmaceutical company, knew doctors were prescribing Neurontin for off-label use, we cannot infer, solely from his position, that he knew they were prescribing it for the specific conditions covered by the '479 patent.[12] Because there is no evidence that defendants knew pharmacists would dispense their gabapentin product to people being treated for the neurodegenerative diseases disclosed in the '479 patent, they cannot be held liable for inducement on that basis.

Even if defendants did not know that Neurontin was being dispensed for neurodegenerative diseases, plaintiff contends that they can still be held liable for inducement because they could easily have discovered that fact had they reviewed data that was readily available to them. In other words, plaintiff says defendants should have known that their product would induce infringement of the '479 patent because they could have discovered, had they conducted an appropriate investigation, that Neurontin was being prescribed for neurodegenerative diseases. Liability for inducement, however, is premised on intentional encouragement of infringement, not inadvertent facilitation of it. See Manville Sales Corp, 917 F.2d at 553; see Oak Indus., Inc. v. Zenith Elec. Corp., 697 F.

---

[11]There are no page numbers on the Court's copy of the Sherman deposition excerpt submitted by plaintiff. Our cites, therefore, reflect the sequence in which the pages appear in that excerpt.

[12]Such an inference would be particularly inappropriate in this case, given the infrequency with which Neurontin is prescribed for neurodegenerative diseases. (See Pl.'s LR 56.1(b)(3)(A) Stmt. ¶¶ 68-69 (admitting that only 2.1% of the more than 3.5 million Neurontin prescriptions written between August 1999 and July 2000 were for neurodegenerative diseases).)

Supp. 988, 993 (N. D. Ill. 1988) ("Courts have held that inducement requires active steps knowingly taken – knowingly at least in the sense of purposeful, intentional, as distinguished from accidental and inadvertent.") (internal quotation marks and citation omitted). Thus, absent evidence that defendants intentionally remained ignorant so they could profit from the use of gabapentin for neurodegeneration, their failure to investigate will not render them liable for inducement.

The record contains no such evidence. There is nothing, for example, to indicate that Dr. Sherman customarily obtains prescribing data before approving the development of a generic drug, but did not do so in this case. Nor is there evidence to suggest that he regularly reviews literature that contains such information, but ignored the data on Neurontin. Because there is nothing to suggest that defendants' failure to investigate Neurontin's uses constituted intentional encouragement of infringement, that omission provides no basis for holding defendants liable for inducement.

Conclusion

For the reasons set forth above, there is no genuine issue of material fact on plaintiff's claim that defendant's proposed gabapentin product will infringe the '479 patent. Accordingly, defendants are entitled to judgment as a matter of law on the second patent infringement claim plaintiff asserts against them. Defendant's motion for summary judgment on that claim is, therefore, granted. This is a final and appealable order.

ENTER:

UNITED STATES DISTRICT JUDGE

DATED: 9-13-01